May 2024

The implementation of the European Regulation on In-Vitro Diagnostic Medical Devices (IVDR 2017/746/EU), which came into force on May 26, 2017, is progressing rapidly at DiaSys Diagnostic Systems GmbH.

By appointing the responsible Notified Body and by passing the first IVDR audit in 2021, DiaSys has fulfilled all requirements necessary to implement the IVDR successfully.

A team of dedicated employees is continuously committed to achieving IVDR compliance for DiaSys products. As already communicated, the submission for certification takes place in several waves.

Product files of the first defined wave have been submitted to the Notified Body for testing and certification, further product files are being processed to ensure the future availability of the products under the new regulation.

At the moment, DiaSys is not in a position to give a timeline for the complete implementation of the IVDR.

We appreciate your understanding that DiaSys is depending on the Notified Body, i.e. IVDR compliant products can only be provided once the Notified Body has issued the certificate, all labeling adjustments and the corresponding logistics planning has been done.

DiaSys is fully committed to the goal of full IVDR implementation. We will keep you regularly informed about the current certification status https://www.diasys-diagnostics.com/qm/ivdr/.